UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE, Plaintiff, v. IMSTEM BIOTECHNOLOGY, INC., XIAOFANG WANG, and REN-HE XU, Defendants.	C.A. No. 1:17-cv-12239

DEFENDANTS' RESPONSE TO ASTELLAS' POST-TRIAL PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

Astellas' post-trial submission is unfortunately emblematic of the behavior that gave rise to this lawsuit. Astellas has again downplayed Dr. Xu and Wang's scientific acumen, misconstrued basic facts, talked past the real issues, and overlooked its own errors in the collaboration and the litigation. This is regrettable. The Court should look past Astellas' heated language and instead credit the good ideas and inventions that Drs. Xu and Wang contributed.

RESPONSES TO ASTELLAS' PROPOSED FINDINGS OF FACT

Astellas misconstrues countless pieces of testimony and evidence in an apparent effort to undermine the Defendants' credibility. The effort fails. A few examples illustrate why:

- Astellas seizes on an alleged inconsistency between (i) Dr. Wang's offhand statement in an email that working with the EAE model would be "easy" and (ii) his and Dr. Bunnell's trial testimony about the difficulties in setting up the EAE model. ECF 243 ("AFOF") ¶ 13. In fact, there was no dispute. Dr. Wang had put in considerable time and effort to learn the model, Tr. 6-44:7 to 6-45:18, whereas it was not "easy" for someone like Dr. Kimbrel who had no experience with multiple sclerosis or the model. Tr. 6-45:1-2 ("It's easier for me, maybe if you trained enough, but it's not easy for everybody."); *see* Tr. 2-94:17:19; 6-44:7 to 6-45:18; *cf.* Tr. 7-52:2 to 7-54:14.

- Astellas claims that Dr. Wang "walk[ed] back or recharacterize[d]" admissions about the state of the art regarding use of MSCs with the EAE model. AFOF ¶ 12. Not so. Dr. Wang pointed out that Dr. Fortier's "handpicked" papers overstated the science. Tr. 6-97:2-14. The parties' joint paper, which Dr. Fortier ignored, stated that the effect of older MSCs on the EAE model was "mild or negligible." Tr. 6-97:15-25; TX-9 at 123; *see infra* note 8. The underlying science was and is messy. Compounding the confusion, Dr. Fortier was overstating the art as of 2009; Dr. Wang was responding to language from a patent filed in 2013. TX-A. Astellas and Dr. Wang were talking past each other (again).

- Astellas breathlessly suggests Dr. Wang "reversed course 180º" between direct and cross when referring to his first "BIO" GSK3i experiments, reciting a short story on direct and "adding" details only on cross. AFOF at 1, ¶ 37. In fact, Dr. Wang testified about the experiments as he remembered them on direct. Tr. 2-216 to 2-217 ("exciting discovery"). He added details on cross regarding the date he ordered supplies and then titrated, including points he hadn't recorded at the time. Tr. 6-215:12 to 6-216:4. Of course Dr. Wang obtained the BIO prior to using it; of course he did not write down every mechanical step. *See* Tr. 6-215:23 to 6-216:4.[1] There is nothing here.

[1] Nor is 10 days and two experiments too short a time to invent; Astellas says one email is enough. *Cf.* AFOF ¶ 1.

- Astellas suggests an inconsistency between Dr. Xu's deposition testimony concerning the collaboration yielding a "shortcut . . . *to test*" and his trial testimony concerning "animal *testing*." AFOF ¶ 54 (emphasis added); *id.* at n. 10. Not true. As he explained, the collaboration had precipitated a UConn animal permit that, once in place, was available (earlier) for everyone. There was no scientific link between the HB-MSCs and T-MSCs that were being tested on those animals. *See* ECF 244 ("DFOF") ¶¶ 118–20.

For all the rhetorical flourish, there is simply nothing wrong here. Dr. Xu and Wang's trial testimony was consistent and credible.

Turning to the merits, Astellas makes a series of incorrect factual statements concerning the '956 patent. First, Astellas asserts that Lanza conceived of the application of a new cell to treat the full range of pathologies listed in Claims 3 and 4 of the '956 patent – in one question in one email in September 2009. AFOF ¶ 1.[2] The Court should reject this assertion. For starters, it lacks proper evidentiary support. Dr. Lanza never actually testified that he invented the claimed *uses* in September. *See* Tr. 1-100:14 to 1-103:10 (cited in AFOF ¶ 1 (second sentence)). He testified that (i) he wanted to "make" a cell and (ii) another cell had certain properties, but not as to "use" in September 2009. *Id.;* AFOF ¶ 1 ("make"). Instead, Astellas cites Dr. Fortier to fill that factual omission and claim that Lanza "came up with the idea of using HB-MSCs to treat multiple sclerosis" in September 2009. AFOF ¶ 1 (third sentence). Dr. Fortier "opine[s]" on the matter. *Id.*[3] This is improper. Dr. Lanza was available to testify. The parties had documents (one email from Lanza in 2009, TX-38; a dozen from the Defendants in 2010, *e.g.* TX-11, 16). Yet Astellas used an expert to stand in for an evasive fact-witness.[4]

[2] Astellas confuses the invention of the '956 patent with invention of the '321 patent. *See, e.g.*, AFOF ¶¶ 1-2 (intertwining Lanza's alleged conception of use ('956) with Kimbrel's work on making ('321)). The claims are different; the patents are different. TX-1, TX-2. *See Philips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (claims define the invention); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (same).

[3] Astellas also inexplicably points to testimony about testing *after* Kimbrel had reduced to practice. AFOF ¶ 2.

[4] *See* ECF 184 (MIL) at 4-6 (cases cited) (expert testimony that merely gives the expert's stamp of approval to fact testimony as unhelpful under Rule 702). Indeed, Astellas originally planned an even larger role for Dr. Fortier, testifying on matters from who-did-what, to credibility, to legal analysis – all of it beyond her ken. *Id.* at 3-7. Dr.

As important, Astellas never explains how Lanza's one-line query amounts to complete conception. AFOF ¶ 1 (citing TX-38). Lanza did not say, "I have a firm and definite idea about new cells that will treat all of the diseases listed in the attached article." The cells did not exist yet. TX-38. Lanza expressed nothing beyond "hope." *Cf. Burroughs Wellcome Co. v. Barr Labs, Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994) (hope is not enough). Nor did he call out every disease in the article. TX-38. Certainly not multiple sclerosis. Nor treatment. *Id*. Astellas offers no other corroborating documents showing a definite and permanent idea of treating multiple sclerosis in 2009. AFOF ¶¶ 1-3.

This may explain why, after saying that Lanza came up with the idea, Astellas turns around and says it was obvious. AFOF ¶ 10. Astellas errs here too, overstating the prior art. Dr. Fortier's first tranche of cited art (*see* AFOF ¶ 10 at third sentence) is all directed to MSCs derived from adult tissues, not MSCs derived from embryonic stem cells, and certainly not these "MSCs" derived from embryonic-stem-cells-by-way-of-embryoid-bodies-then-by-way-of-hemangioblasts.[5] Dr. Fortier's second tranche of cited art (*see id*. at fourth sentence) is primarily directed to safety and/or contains only limited data. Tr. 6-98:15-24; Tr. 6-149:22 to 6-150:24.[6] As Drs. Bunnell and Perry testified, MSCs derived from different sources may be different to the

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Fortier narrowed her testimony at trial (presumably in response to the Court's observation that she was not a lawyer, ECF 163 (SJ) at 19) but Astellas nevertheless asked her to vouch for and/or bless "facts" fed to her by counsel. Tr. 3-23:23 to 3:24:12 (objection to Dr. Fortier being shown slides before testifying). Defendants, by contrast, asked their experts to explain science and scientific significance. They testified to assist, not supplant, the fact-finder.

[5] *See* TX-60 at 1755 ("Materials and methods") (mouse BM-MSCs); TX-HU at 17 ("Materials and methods") (BM-MSCs); TX-HE at 220 ("Methods and materials") (mouse BM-MSCs); TX-HJ at 754 ("Methods – Bone Marrow MSC Isolation") (mouse BM-MSCs); TX-58 at 2 ¶ 2 (BM-MSCs).

[6] *See* TX-HL at Abstract ("We can claim that the injection of expanded MSC is a safe procedure"); TX-HM at Conclusion ("This preliminary report emphasizes the *feasibility* of autologous MSC for treatment of MS patients. However, in order to draw a definitive conclusion a larger sample size is required.") (emphasis added); TX-HS at Abstract (no clinical trial; "Based on the *preclinical* data, we are currently evaluating the safety of a similar therapeutic approach . . ."); TX-HK at 644 ("reporting a successful use of umbilical-cord-derived-MSCs, but noting that "many immunomodulatory or immunosuppressive strategies have been used for [MS] control, showing no or only partial effectiveness" as of 2009). One of the references extolled BM-MSCs, effectively teaching *away* from hESC-derived cells like the ones here. *See* TX-HI at 889 (no clinical trial) and 893 ("Conclusions").

point of rendering the "MSC" label being meaningless. Tr. 7-38:13 to 7-39:3; 7-39:25 to 7-40:6; 8-67:21 to 8-68:9; 8-68:19-25. Defendants said nothing to the contrary. *Contra* AFOF at ¶ 10.

With respect to mitotic inactivation, Astellas does not dispute that the Defendants first conceived the notion of mitotically inactivating the new cells, AFOF ¶¶ 21-22, but instead contends the notion was taught in the prior art and doing so here was obvious. *Id.* In fact, all five references cited by Dr. Fortier in AFOF ¶ 21 involved *in vitro* analysis, not animal studies.[7] *In vitro* studies were not predictive of *in vivo* work; the translation was hardly so certain as to be well-established or obvious. Tr. 7-62:12-25 ("[W]e busted the DNA all to hell. ... It may not function the way it once was"). Astellas' assertion that Dr. Fortier (not an expert in MSC culturing or multiple sclerosis) is "unrebutted," AFOF ¶ 21, is not true. Tr. 7-62:12 to 7-68:2. Likewise, none of her "ESC-derived cell" references involved MSCs.[8]

With respect to IL-6, Astellas asserts that Kimbrel "recognized" the role of IL-6 and was therefore the first to make this contribution. AFOF ¶ 19. Astellas relies on TX-NI, even though Kimbrel expressed no grasp of IL-6 in that email. *Id.* Astellas then asserts that Kimbrel made an "observation" regarding IL-6, but her original March presentation neither circled nor commented upon IL-6. TX-62 at AIRM297365-369. The August email (TX-NI) also undercuts Astellas' assertion that IL-6 is inherent (and allegedly claimed as such in the patents), since it notes that young and old MSCs behave differently, *id.* at 1 – a phenomenon that Dr. Wang was busily examining and exploiting (*i.e.* screening) even as Dr. Kimbrel did not "follow[] up on it." TX-

[7] *See* TX-GS at 3 ("Materials and methods"); TX-HA at 2 ("Materials and methods"); TX-HX at Abstract ("in vitro"); TX-HC at Abstract ("in vitro"); TX-GY at 1 ("Method") ("in vitro").

[8] Further: (i) TX-GZ cited the problem of tumorigenesis but offered no solution, never citing mitotic inactivation; *id.* at 1790 ("Clearly much more work is going to be needed"); (ii) TX-HG involved regenerative use, not immunosuppression and it was "unclear whether mitotically inactivated ES cells could retain their full functionality;" *id*. at 1087; and (iii) TX-HB said the "effects on the desired cell population is unclear;" *id*. at 26 at Table 1 (c) General manipulation.

RP. Kimbrel mused that figuring out cytokine differences would someday be "great for intellectual property and patent protection," but that particular "[H]oly [G]rail" eluded her, TX-NI, that is, until Dr. Wang explained the significance of IL-6 to her. TX-PH (Nov. 2011 email from Dr. Wang); TX-9 at 1 (joint paper, drafted by Xu and Wang, explaining IL-6 in MSCs).

With respect to GSK3i, Astellas dismisses feeder-free systems as "routine" and a "business decision." AFOF ¶ 35. Not only does this misapprehend the nature of invention generally (inventions are novel combinations of existing elements; *see In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000)), it deliberately sidesteps what happened, here, in this recipe. This brand new "MSC" recipe had never been adapted to a feeder-free system. DFOF ¶ 43 (Kimbrel used feeder cells). Dr. Wang tried something different (a feeder-free, defined culture) and found he needed to try a new and counter-intuitive combination of existing elements to make it work well. *Id.* ¶ 44. Dr. Kimbrel's dismissal of the combination (in which she had no experience, Tr. 2-103:2) is belied by her own lab's struggles with the same problem when it tried to convert to feeder-free production in early 2010 (after Wang). Tr. 2-100:20-22; TX-EV at 3 ("Current Problems . . . 2. Massive cell death (90%)").

Astellas also asserts that the PTO Examiner did not do a good job evaluating the importance of GSK3i in the '551 patent. AFOF ¶¶ 42-44. The assertion fails. Astellas never provides evidence that an additional Examiner's search for "GSK3" or "BIO" would have uncovered relevant art. *Id.* Nor does Astellas explain why Brivanlou's later publications (2006 and 2009) would have changed the outcome. The 2006 paper was "exactly" the same as the 2004 paper in terms of teaching "maintaining human embryonic stems cells (hESCs) in the undifferentiated state," Tr. 4:55:2-15; TX-34 at 115. The 2009 patent publication likewise taught a method of "maintaining the undifferentiated state of an embryonic stem cell." TX-33 at ¶ 0005

("Summary of the Invention"). Both taught what the 2004 paper already disclosed: that GSK3i should be used to *prevent* differentiation, the opposite of Defendants' notion of *promoting* cell differentiation downstream into EBs, HBs, and MSCs.[9]

With respect to its Ch. 93A claim, Astellas makes various points about the grants that Drs. Xu and Wang sought on behalf of the collaboration. AFOF ¶¶ 45, 51-53.[10] Astellas does not show any wrongdoing or harm. Astellas knew the Defendants were applying for grants to fund the project. *See, e.g.*, TX-MJ at 13. Defendants raised and contributed over $2M to help the collaboration. Tr. 10-228:15-18; 6-10:1-6; 6-237:22 to 6-238:3.[11] Further, Astellas never explains whether or how the Kimbrel data in the 2013 grant application, TX-AV, was different or more meaningful than what Dr. Kimbrel had already knowingly provided for a similar grant in December of 2010. TX-22. Finally, Astellas points to an email exchange in which Dr. Wang asks to use ACT's data in a UConn presentation. AFOF ¶ 45; TX-GW. Dr. Wang's testimony was not "inconsistent" with the "plain language" of the email. *Contra* AFOF ¶46 (citing *inter alia* TX-39). The email was part of a string titled, "[D]ata and info *for grants*" TX-39 (emphasis added). There is nothing here.

Astellas relies on self-serving and uncorroborated assertions about other collaborators, presumably to suggest they agreed to forfeit their patent rights in exchange for the privilege of writing a joint paper with ACT. AFOF ¶¶ 6-9. But Astellas provides no evidence regarding those

[9] Astellas' argument regarding Dr. Brivanlou's extremely large range GSK3i doses also falls short. AFOF ¶ 43. Even assuming that this vast range somehow captured Defendants' use, the *purpose* differed.

[10] Defendants addressed the patent filing, investor solicitation, and T-MSCs in their opening brief. DFOF ¶¶ 89-152. With respect to grants, Astellas faults "Defendants counsel" for an error in ECF 221 ¶ 84 (asserting the grant made no mention of HB-MSCs). AFOF ¶ 51. No one advanced or defended the error at trial.

[11] As Dr. Xu explained, Imstem used some of the 2013 grant money to finish the collaboration and some to further its own T-MSC research. Tr. 10-202:11 to 10-203:13. Dr. Xu did not contradict Mr. Green; the grant was used for both purposes. *Contra* AFOF ¶ 51. There is no skullduggery here.

collaborations, the scope of their MTAs, or whether anyone invented anything. And ACT's own draft MTA acknowledged that collaborators can invent, as Drs. Xu and Wang did here.[12]

Astellas also points to Defendants' initial interrogatory responses (TX-XZ) as if they, not the amended responses (TX-FB), somehow reflect the facts of the case. Not so. Amendment is entirely proper as a case progresses. Fed. R. Civ. P. 26(e). Dr. Wang's heightened focus as the case became more burdensome and Astellas refused to settle, Tr. 6-265:25 to 6-266:2, was normal in light of the strain the litigation has placed on ImStem. Tr. 6-265:18 to 6-266:2; 6-266:19-22. The calculus of effort and expense changed over time.[13]

RESPONSES TO ASTELLAS' PROPOSED CONCLUSIONS OF LAW

With respect to the inventorship of Claims 3 and 4 of the '956 patent (multiple sclerosis), the record above demonstrates that Lanza did not have "a definite and permanent idea of the invention as it will be used in practice" before Xu and Wang (a multiple sclerosis expert) entered the collaboration. *Burroughs Wellcome*, 40 F.3d at 1228. Lanza had a vague query, at best a "general goal" or "research plan," that never mentioned multiple sclerosis. *Id.* It was the Defendants who first fully conceived the "definite and permanent" idea to target MS – the invention claimed in the '956 patent. Tr. 6-40:14-19; Tr. 10-31:14-21. Their contribution was thus inventive. *Univ. of Pittsburgh v. Hedrick*, 573 F.3d 1290, 1298 (Fed. Cir. 2009).[14]

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[12] Astellas' attempts to downplay the importance of the MTA here (AFOF ¶ 47 n. 9) but it was ACT's Matt Vincent who decided to take the "patent off the table" *after* ACT had already copied and pasted large amounts of Defendants' 2011 grant application into the '321 patent. *See* DFOF ¶ 102.

[13] *See* Fed. R. Civ. P. 26 Advisory Cmte. Notes at 1970 Amendment (Subdivision (e) – Supplementation of Responses) ¶ 2 ("Although the party signs the answers, it is his lawyer who understands their significance and bears the responsibility to bring answers up to date.")

[14] Even if Lanza had considered application of this novel cell type to multiple sclerosis in September 2009 (he did not), that would not render Defendants' contributions not worthy of inventorship. *Dana-Farber Cancer Inst., Inc. v. Ono Pharm. Co.*, 379 F. Supp. 3d 53, 94 (D. Mass. 2019), a*ff'd*, 964 F.3d 1365 (Fed. Cir. 2020) ("The fact that the Court cannot attribute this contribution to Dr. Freeman or Dr. Wood individually by clear and convincing evidence does not doom their joint inventorship claim. The trio's simultaneous focus on blocking the pathway to treat cancer in early 2000 shows that they were all working toward a shared goal. . . .")

Dr. Fortier overstates the prior art. This was (and is) a messy field; MSC features ranging from *in vitro* secretions to *in vivo* cell function and mobility were unpredictable. *See* DFOF ¶ 54; Tr. 7-59:18 to 7-61:12. The Examiner implicitly agreed, deeming the claimed methods of using HB-MSCs to be free of the prior art. ECF 37 at 10.[15] Astellas' argument to the contrary, AFOF ¶ 66, amounts to the self-defeating assertion that that the concept of using the cells was itself obvious. *See* DFOF ¶¶ 198-200. The '956 patent is directed to using cells, not generating them, nor merely "characterizing" them. *See* ECF 28 (Oppn. Mot. to Dismiss) at 7-8 (history of Astellas' election to pursue '956 and '321 patents as separate patents, one for using, one for making); 35 USC § 101 (distinguishing between "process" and "composition of matter" claims). As important, no amount of art can turn Lanza's email into "conception." *Cf.* Tr. 3-145:16-23.

Astellas' points regarding corroboration (AFOF ¶ 68) are wrong; Defendants have pre- and post-conception emails (TX-11, TX-16) and opponent admissions/corroboration (Tr. 2-91:20; Tr. 2-32:9-16). *Compare Gen. Elec. Co. v. Wilkins*, 750 F.3d 1324, 1332 (Fed. Cir. 2014) (no supporting documentation); *Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n*, 383 F.3d 1352, 1383 (Fed. Cir. 2004) (only limited and ambiguous documentation).

With respect to IL-6, Astellas misinterprets the claims of the '956 patent, which do indeed claim preferential selection and thus "screening" of certain cells (a term Dr. Fortier employed during her own analysis, *see, e.g.*, Tr. 3-76:18-24). Claim 1 encompasses all hemangioblast-derived mesenchymal stem cells, regardless of the character of those cells (*e.g.* high or low IL-6, high or low CD10, young or old, etc.). The claim is agnostic as to cell features and is thus broad; any amount of IL-6 would infringe that claim. Claim 9, by comparison, specifically employs low IL-6 as a separate limitation. Only those cells that meet a low IL-6

[15] The Court noted early in the case that there could be no conclusion that the treatment of MS using HB-MSCs was obvious in light of the prior art. (ECF 37 at 10-11). Trial has reinforced the point.

threshold (*i.e.* screen) – a desirable subset identified by Drs. Xu and Wang – infringe claim 9. *Clearstream Wastewater Systems, Inc. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446 (Fed. Cir. 2000) ("Under the doctrine of claim differentiation, it is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims."). Astellas/Dr. Kimbrel's characterization of IL-6 as an inherent "fingerprint," Tr. 3-78:21-25, fails to grasp the invention as claimed. Under her reading, claim 9 would be superfluous.

Defendants' contributions were far more than reduction to practice; it was investigation of the critical steps that made MS treatment viable; understanding of the effects of those steps in the body; guiding the application of the method to the treatment of MS. This is conception.[16] *Dana-Farber Cancer Inst.*, 379 F. Supp. 3d at 9; *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 12 F. Supp. 2d 69, 85 (D. Mass. 1998), *aff'd*, 225 F.3d 1315 (Fed. Cir. 2000); *see CardiAQ Valve Techs., Inc. v. Neovasc Inc.*, No. 14-CV-12405-ADB, 2016 WL 6465411, at *18 (D. Mass. Oct. 31, 2016), *aff'd*, 708 F. App'x 654 (Fed. Cir. 2017).

Astellas' assertion that the Court may not determine Dr. Xu and Wang's inventorship by "comparing" their contributions to Dr. Kouris's CD10 characterization is twice wrong. First, the lone and unreported case that Astellas cites, *Tavory v. NTP, Inc.*, 297 F. App'x. 976, 981 (Fed. Cir. 2009), presents an entirely different fact pattern. Defendants are not claiming, as the plaintiff did in *Tarvoy*, that they (rather than Dr. Kouris) came up with the idea of characterizing HB-MSCs' CD10 expression.[17] Rather, Defendants' contend that Dr. Kouris' characterization of CD10 – which Defendants do not dispute is inventive in the context of HB-MSCs – is a useful

[16] For the reasons discussed in the *Dana-Farber* and *PerSeptive* decisions, this also defeats Astellas' argument that Defendant's contribution was mere reduction to practice. AFOF ¶ 69.

[17] The language Astellas cites is in any event dicta. *Tavory* turned on failure-of-proof issues which are not relevant here because Drs. Xu and Wang memorialized their contributions in grant applications and lab notebooks, the accuracy of which Astellas has never questioned.

measuring stick for Drs. Xu and Wang's greater contributions to the '956 and '321 patent as claimed.[18] Second, Astellas' argument asks the Court to ignore Dr. Kimbrel's testimony that Dr. Kouris' inventive contribution to the '321 and '956 patents was his observation and recording of the CD-10 surface marker. Tr. 2-117:22 to 2-118:8; Tr. 5-96:21 to 5-99:4 (no reason to doubt Dr. Kimbrel's deposition testimony).[19] Dr. Kimbrel was the person at Astellas who worked with Astellas' attorneys to prosecute the '321 and the '956 patents. *See* Tr. 1-152:4-16 (Dr. Lanza) ("it was the lawyers and Dr. Kimbrel" who made the inventorship determinations); *see also* Tr. 5-113:8-19; Tr. 5-122:5-8. Although Astellas now claims, in essence, that Dr. Kimbrel did not know what she was talking about in her sworn deposition testimony, Astellas did not adduce any evidence during trial regarding any other contribution(s) by Dr. Kouris that made their way into the claims of the '321 or '956 patents. Astellas' failure to tie Dr. Kouris's (impressive) background or his work at ACT to the inventions of the '321 and '956 patents (as reflected in the claims) dooms its vague suggestions of other inventive contributions by Dr. Kouris.

Finally, with respect to the Ch. 93A claim, Astellas errs in relying upon the *Mass. Eye & Ear Infirmary* ("*MEEI*") litigation. *See, e.g.*, AFOF ¶ 89. *MEEI* is inapposite on several grounds; it dealt with a (i) a fully-executed MTA and (ii) a patented treatment that was commercialized; and (iii) simultaneous 93A and unjust enrichment claims. *Massachusetts Eye & Ear Infirmary v. QLT Phototherapeutics, Inc.*, 412 F.3d 215, 222-225 (1st Cir. 2005)("MEEI I"). None of these is present here.[20]

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[18] If Astellas really believed that Dr. Kouris' testimony was "irrelevant to the issues before the Court," AFOF ¶ 76, it could have objected to his testimony at trial. It did not.

[19] Dr. Kouris candidly admitted that he was "surprised" when he found out he was a named inventor on the '956 and '321 patents because, among things, he "did not believe" that he was going to be a named inventor at the time he gave his CD10 data to Dr. Kimbrel. Tr. 5-120:8-19.

[20] That case's procedural history is tortured and counsels against overreliance on it. *MEEI* I was appealed to the First Circuit, appeal decided, appeal reheard, opinion rewritten, remanded in part, appealed again, and the decision was later clarified on denial for rehearing. *Compare MEEI I,* 412 F.3d at 225 *with Massachusetts Eye & Ear*

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Infirmary v. QLT Phototherapeutics, Inc., 552 F.3d 47, 50 (1st Cir.), *decision clarified on denial of reh'g*, 559 F.3d 1 (1st Cir. 2009) ("MEEI II"). A more analogous and timely decision for the Court's consideration is *Dana-Farber Cancer Inst.*, discussed *supra* n. 13.

CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2020, I caused a true copy of the foregoing document to be served upon all counsel of record via the Court's CM/ECF electronic filing system.

/s/ *Timothy R. Shannon*
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